

OCT 09 2002

### **XIII. SUMMARY OF SAFETY AND EFFECTIVENESS**

***Allegiance***

K023170

#### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS NITRILE POWDER-FREE EXAMINATION GLOVES**

**Applicant/Sponsor:** Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, IL 60085

**Regulatory Affairs Contact:** Erica Sethi  
Allegiance Healthcare Corporation  
1500 Waukegan Road, Bldg. WM  
McGaw Park, IL 60085

**Telephone:** (847) 785-3337

**Date Summary Prepared:** September 10, 2002

**Product Trade Name:** Undetermined

**Common Name:** Examination Glove

**Classification:** Patient Examination Glove

**Predicate Devices:** Flexam Nitrile T Ambi Examination Gloves, Allegiance Healthcare Corp.

**Description:** Nitrile Powder-Free Examination Gloves are formulated using nitrile and offered powder-free.

**Intended Use:** These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

**Substantial Equivalence:** Nitrile Powder-Free Examination Gloves are substantially equivalent to Allegiance Healthcare's Flexam Nitrile T Ambi Examination Gloves in that they provide the following characteristics:

- same indication for use
- same sizes
- both made of nitrile
- both offered beaded and powder-free

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Gloves show no irritation.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Tensile Strength	Gloves meet or exceed requirements per ASTM D6319-00a.
Barrier Defects	Gloves meet or exceed requirements per 21 CFR§800.20 and ASTM D6319-00a.



OCT 09 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Erica Sethi  
Manager, Regulatory Affairs  
Allegiance Healthcare Corporation  
1500 Waukegan Road, Building WM  
McGaw Park, Illinois 60085

Re: K023170

Trade/Device Name: Nitrile Powder-Free Examination Gloves  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Gloves  
Regulatory Class: I  
Product Code: 80 LZA  
Dated: September 10, 2002  
Received: September 23, 2002

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

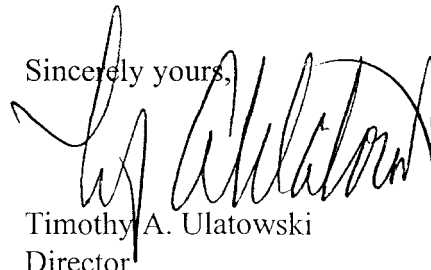
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", is written over the typed name and title.

Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, Illinois 60085-6787  
847.473.1500  
FAX: 847.785.2460

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Applicant: Allegiance Healthcare Corporation

510(k) Number: K023170

Device Name: Undetermined *Nitrile Powder-Free Examination Gloves*

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

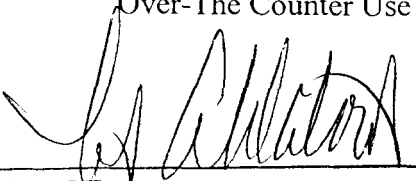
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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: \_\_\_\_\_

*K023170*